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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,520	07/26/2004	Woong-Sig Moon	038779/280751	5680

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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT	PAPER NUMBER
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1655

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/502,520

Applicant(s)

MOON ET AL.

Examiner

Christopher R. Tate

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8,12-20 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1, 2, 4-8, 12-20, and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed 25 January 2007 is acknowledged and has been entered. Claims 1, 2, 4-8, 12-20, and 22 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1, 2, 4-8, 12-20, and 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Picard-Lesboueyries et al. (US 2002/0058010) and Uchida et al. (JP 58023612 - DWPI, JPAB, and CAPLUS English Abstracts thereof), in view of Sanchez et al. (US 5,296,472) for the reasons set forth in the previous Office action.

Applicants' arguments concerning the art rejection above (as they apply to the amended claims) have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants argue the references individually as follow: that the Picard-Lesboueyries et al. reference is directed to foaming compositions for treating greasy skin or acne-prone skin (containing Moutan root extract therein) and that this reference provides merely a generalized statement that antimicrobial agents may be chosen from antibiotics and antifungal agents but that this reference is primarily concerned with treating bacteria acne; that the Uchida reference teaches a composition (containing Moutan root bark extract therein) which exhibits improvements to the skin including for pimples, etc. but that Uchida is silent regarding adding an anti-fungal thereto; and that Sanchez provides compositions for delipidation of skin which can include an antimicrobial but is also silent regarding adding an anti-fungal thereto.

However, Applicants have argued and discussed references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the references - for the reasons set forth in the previous Office action which is restated below.

Picard-Lesboueyries et al. beneficially teach an anti-acne cosmetic (as well as cleansing and medicinal) composition which comprises, or may comprise, antimicrobial compounds (such as triclosan, nystatin, tolnaftate), an extract of *Paeonia suffructicosa* root (Moutan root) - obtained from a commercial supplier, and other conventional cosmetic ingredients (such as fillers, fragrances, moisturizers, and propylene glycol) therein (see, e.g., Abstract, paragraphs [0007], [0072]-[0073], [0078], [0107], 0109], and claims). Please note that an extract of *Paeonia suffructicosa* root would appear to intrinsically comprise the root bark (cortex) since the root bark is a natural part of the root and Picard-Lesboueyries et al. do not teach that the root bark was removed therefrom. Picard-Lesboueyries et al. do not expressly teach how the *Paeonia suffructicosa* root was extracted, or the inclusion of certain other ingredients therein.

Uchida et al. beneficially teach a skin cosmetic (as well as cleansing and medicinal) composition (e.g., for treating acne), in the form of a cream, which comprises an aqueous (water) or aqueous-ethanolic extract obtained from the root bark of *Paeonia suffructicosa* (also termed Moutan root bark) as the active ingredient therein (see DWPI, JPAB, and CAPLUS English Abstracts). Uchida et al. also disclose that their composition comprises propylene glycol (a "skin

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moisturizer"), lanolin (a "skin permeation enhancer"), perfume (a "fragrance") - all within the instantly claimed amount ranges. Neither of the cited primary references expressly teaches the inclusion of dextrin or cyclodextrin therein.

Sanchez et al. beneficially teach that cyclodextrin-containing compositions can be topically used to effectively treat acne (since cyclodextrins are rather resistant to common amylolytic enzymes present in microorganisms of the human skin). Sanchez et al. also beneficially disclose that it is well known in the art to use cyclodextrins to encapsulate fragrances (see entire document including col 1, lines 55-56, and col 7, lines 3-8).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare an anti-acne composition comprising an extract (including an aqueous or aqueous-ethanolic extract) obtained from the root bark of *Paeonia suffruticosa* as an active ingredient therein in combination with another art-recognized antimicrobial compound (such as one of those disclosed by Picard-Lesboueyries et al) based upon the beneficial teachings provided by the two cited primary references with respect to the anti-acne activity such compositions afford, as discussed above. It would also have been obvious to one of ordinary skill in the art at the time the claimed invention was made to include cyclodextrin therein since Sanchez beneficially teaches that cyclodextrins are useful against acne and the acne-causing microorganisms, and also because Sanchez further discloses that cyclodextrins are conventionally used in the art to encapsulate fragrances - which both of the primary reference anti-acne compositions contain. The adjustment of this and other conventional working conditions (e.g., including other conventionally employed cosmetic ingredients therein including a particular conventional fragrance or filler, using a conventional topical form such as within a

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spray applicator, and/or determining appropriate result-effective amounts of such ingredients) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Please also note that such a composition would intrinsically provide the instantly claimed functional activities (e.g., provide antimicrobial activity against the various recited microorganisms).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of clear and convincing evidence to the contrary.

Claims 1, 2, 4-8, 12-20, and 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. (JP 10194916 - Full computer English translation thereof) and Nishibe et al. (JP 09158042 - Full computer English translation thereof), in view of Picard-Lesboueyries et al. (US 2002/0058010), and further in view of Sanchez et al. (US 5,296,472) for the reasons set forth in the previous Office action which are restated below.

Applicants' arguments concerning the art rejection above (as they apply to the amended claims) have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants argue the references individually as follow: that the Mori et al. reference is directed to a cosmetic (containing Moutan root bark extract therein) having antimicrobial action while not irritating or sensitizing the skin, but that Mori et al. is silent regarding adding an anti-

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fungus thereto; that the Nishibe et al. reference is directed to textile treating agent including a Moutan root bark extract which is useful for preventing bacteria and mold breeding in/on textiles which can lead to skin inflammation; that the Picard-Lesboueyries et al. reference is directed to foaming compositions for treating greasy skin or acne-prone skin (containing Moutan root extract therein) and that this reference provides merely a generalized statement that antimicrobial agents may be chosen from antibiotics and antifungal agents but that this reference is primarily concerned with treating bacterial acne; and that Sanchez provides compositions for delipidation of skin which can include an antimicrobial but is also silent regarding adding an anti-fungal thereto.

Again however, Applicants have argued and discussed references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the references - for the reasons set forth in the previous Office action which are restated below.

Mori et al. beneficially teach a skin cosmetic composition (as well as cleansing and medicinal) composition having excellent antimicrobial activity including against pimples (acne), whereby the composition is in one of various forms including a cream (as well as other topical forms), comprising a water, ethanol, or aqueous-ethanolic extract obtained from the root bark (cortex) of *Paeonia suffruticosa* (also termed Moutan bark) as an active ingredient therein. Mori et al. also beneficially disclose that the composition may include other conventional

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cosmetic ingredients therein including a polyhydric alcohol, propylene glycol, ethylene glycol, glycol ethers, polyethylene glycol esters, sorbitol, lanolin, moisturizers, and perfume (fragrance) as well as other fragrant herbal oils such as orange oil or avocado oil (see entire English translation including Abstract and paragraphs [0012]-[0019], [0021], [0022], Examples).

Nishibe et al. also beneficially teach a skin cosmetic composition (as well as cleansing and medicinal) composition (for internal or external use - including in the form of a liquid or gel) having effective antimicrobial activity (including against bacteria and mold that breed on the body) comprising an extract obtained from the root bark (cortex) of *Paeonia suffruticosa* (also termed Moutan bark), whereby the extract solvent may be water and/or ethanol. Nishibe et al. also beneficially disclose that the composition may include other conventional cosmetic ingredients therein including propylene glycol, ethylene glycol, polypropylene glycol, [0028] glycol ethers, polyhydric alcohol derivatives such as polyhydric alcohol ethylene oxide, and natural perfume fragrances such as lavender, rosemary, spearmint, rose, and/or other herbal oils (see entire English translation including Abstract, and paragraphs [0004], [0007], [0008], [0016], [0028], [0031], [0040], [0067], and Examples/Tests). Mori et al. and Nishibe et al. do not expressly teach the inclusion of certain other claimed ingredients therein.

Picard-Lesboueyries et al. beneficially teach a skin cosmetic (as well as cleansing and medicinal) composition having anti-acne activity including having antimicrobial activity against *Proprioibacterium acnes* - an acne causative microorganism) which comprises, or may comprise, antimicrobial compounds (such as triclosan, nystatin, tolnaftate), an extract of *Paeonia suffruticosa* root (Moutan root) - obtained from a commercial supplier, and other conventional cosmetic ingredients (such as fillers, fragrances, moisturizers, and propylene glycol) therein (see,

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e.g., Abstract, paragraphs [0007], [0072]-[0073], [0078], [0107], 0109], and claims). Again, please note that an extract of *Paeonia suffruticosa* root would appear to intrinsically comprise the root bark (cortex) since the root bark is a natural part of the root and Picard-Lesboueyries et al. do not teach that the root bark was removed therefrom. Neither of the first three references expressly teaches the inclusion of dextrin or cyclodextrin therein.

Sanchez et al. beneficially teach that cyclodextrin-containing compositions can be topically used to effectively treat acne (since cyclodextrins are rather resistant to common amylolytic enzymes present in microorganisms of the human skin). Sanchez et al. also beneficially disclose that it is well known in the art to use cyclodextrins to encapsulate fragrances (see entire document including col 1, lines 55-56, and col 7, lines 3-8).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare an anti-microbial composition (including an anti-microbial composition useful against acne-causing microorganisms) comprising an extract (including an aqueous or aqueous-ethanolic extract) obtained from the root bark of *Paeonia suffruticosa* (i.e., Moutan root) as an active ingredient therein based upon the beneficial teachings provided by the two cited primary references with respect to the anti-microbial activity (including against acne-causing microorganisms) such a Moutan root extract-containing composition affords, as discussed above. It would also have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine such an antimicrobial Moutan root extract composition with an art-recognized antimicrobial compound (such as those disclosed by Picard-Lesboueyries et al) based upon the beneficial teachings provided by Picard-Lesboueyries et al., as discussed above. It would further have been obvious to one of ordinary skill in the art at the

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time the claimed invention was made to include cyclodextrin therein since Sanchez beneficially teaches that cyclodextrins are useful against acne-causing microorganisms, and also because Sanchez further discloses that cyclodextrins are conventionally used in the art to encapsulate fragrances - which all first three reference cosmetic compositions contain. The adjustment of this and other conventional working conditions (e.g., including other conventionally employed cosmetic ingredients therein including a particular filler, using a conventional topical form such as within a spray applicator, and/or determining appropriate result-effective amounts of such ingredients) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Please also note that such a composition would intrinsically provide the instantly claimed functional activities (e.g., provide antimicrobial activity against the various recited microorganisms).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of clear and convincing evidence to the contrary.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970.

The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Christopher R. Tate
Primary Examiner
Art Unit 1655